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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/518,114

03/21/2005

Peter Aranyi

SSL0102 US PCT

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01/28/2009

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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

01/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/518,114 | Applicant(s) ARANYI ET AL. | |
| | Examiner Erich A. Leeser | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23-28,30-35 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 is/are allowed.
- 6) ☒ Claim(s) 21,23-26,28,30-35 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-14-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicant's Preliminary Amendment filed on January 18, 2008, in which Applicant amended claims 21, 23-27 and 44 to be only directed to the elected subject matter; claims 23-24 to depend from claim 21; claims 21 and 27 to delete the term "solvate", 23-26, 28 and 30-35 to more clearly define Applicant's invention, and cancelled claims 22, 29, 36-43 and 45. Claims 21, 23-28, 30-35 and 44 are currently pending and under examination.

Election/Restriction

Applicant has provisionally elected with Group IV, drawn to claims 21-34 and 44, and directed to compounds and compositions of formula (I) containing a pyridine or piperidine.

Applicant argues that "Examiner has not satisfied the requirements for the Restriction Requirement among Groups I-IX" because although Examiner proffered that the inventions are distinct, he did not prove that they are independent. Copied from the MPEP:

803 [R-3] Restriction — When Proper

Under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 802.01, § 806.06, and § 808.01) or distinct (MPEP § 806.05 - § 806.05(j)).

It is clear from the MPEP that an examiner need only make a showing of either independence or distinctness, but both are not required.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Acknowledgement is made that this application is a 371 of PCT/HU03/00041, filed on June 11, 2003.

Information Disclosure Statement

The references disclosed in the IDS dated December 14, 2004 are made of record.

Specification

In the specification at line 27, page 12, Applicant needs to insert the heading:
"Brief Description of the Drawings".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 23-26, 28, 30-35, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- i) In claims 21, 23, 28, 30-34, and 44, the claims are unclear and as such need to be amended to conform with standard U.S. practice. As such, please insert the words “pharmaceutically acceptable” before the word “salt” in each claim. Correction is required.
- ii) In claim 21, the term “tautomer” is unclear. Where in the compounds of formula (I) does Applicant intend for the tautomerization to occur? At what temperature and pH will tautomerization occur? What acids and bases catalyze the tautomerization? Clarification is required.
- iii) In claim 21, the term “isomer” is unclear. Does Applicant intend this term to include positional isomers, structural isomers, stereoisomers, skeletal isomers, diastereomers, enantiomers, cis-trans isomers, conformers, rotamers, geometrical isomers, or some combination of these subgroups? What is the structural formula(e) of the isomer(s)? Do these isomers share similar activity and properties?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 21, 23-26, 28, 30-35, and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

2. Specifically, the claims contain new matter that was added to the claims which does not have clear support in the original specification, claims or drawings. Claim 21 includes the term “piperidino” in the last line of the definition of the R group.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 44 is rejected under 35 USC 102(e) as being anticipated by Aranyi, et al., WO 03/074500. Aranyi, et al. teaches DPP-IV enzyme inhibitor compounds, which include instant compounds. Specifically, the compound Example 4.1., found in Table 4, on page 30 of the reference anticipates the aforementioned claims where R is pyridyl, B is of formula (1), and Y is tert-butoxycarbonyl. The references compounds exhibit the same activity as the compounds of the instant claims. Therefore, the instant claims 44 is anticipated by Aranyi, et al., WO 03/074500.

Allowable Subject Matter

Claim 27 is patentable over Villhauer, WO 98/19998. The reference teaches structurally similar compounds (see compounds of formula I and definition of R, page 2). The claims differ by requiring a bridged bicyclic heterocyclic linker at instant "B" over the N-alkylene- linker of

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the reference. There is no teaching or suggestion to motivate one skilled in the art to modify the prior art linking group and arrive at the instantly disclosed species of claim 27. Therefore, the claim is free of prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624

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